

PATENT
Customer No. 22,852
Attorney Docket No. 04623.0010

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
Markus STORR et al.)	Group Art Unit: 1797
Application No.: 10/572,703)	Examiner: David C. MELLON
Filed: March 17, 2006)	
For: SEPARATING MATERIAL)	Confirmation No.: 5360

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION UNDER 37 C.F.R. § 1.132

I, **Dr. Markus Storr, PhD, Dipl-Chem. (Univ.)**, do hereby make the following declaration:

1. I am a senior scientist and research project manager at Gambro Dialysatoren GmbH in Hechingen, Germany. Gambro is a global medical technology company and a leader in developing, manufacturing and supplying products, therapies and services for chronic and acute hemodialysis, peritoneal dialysis and hepatic care. I have more than 10 years work experience as R&D project leader in the development of synthetic membranes and dialyzers. In my current position I am responsible within the Gambro research organisation for the development of new therapies based on extracorporeal blood purification treatments with membrane and adsorption devices. Please find attached a copy of my curriculum vitae.

2. I am familiar with the invention disclosed and claimed in U.S. Patent Application No. 10/572,703 (the '703 application).

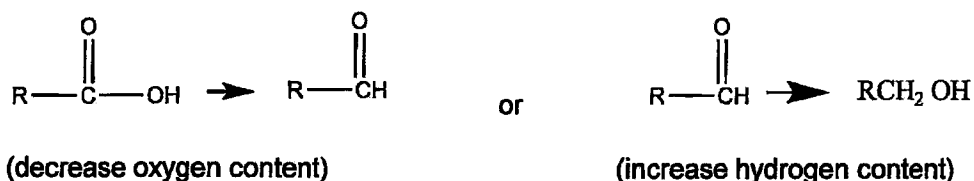
3. I have been informed that the currently pending claims in the '703 application are rejected as allegedly obvious over U.S. Patent No. 5,556,708 to Hörl et al. ("*Hörl*") in combination with various secondary references. Accordingly, I have read the *Hörl* reference.

4. In my opinion, the invention recited in the currently pending claims in the '703 application is not obvious over the cited prior art.

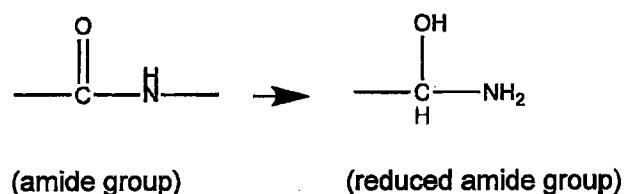
5. The currently pending claims in the '703 application recite a method for producing a separating material by coupling primary or secondary amines on a solid substrate with a thermally labile radical initiator (claim 14), and the separating materials produced by such a process (claim 1).

6. In contrast, *Hörl* describes a method for grafting nitrogen-containing polymers with ethylenically unsaturated monomers in the presence of carbon tetrachloride and a reducing agent. See, e.g., *Hörl* at col. 4, ll. 25-31. *Hörl* uses the reducing agent to form free radicals on the nitrogen-containing polymer in the presence of carbon tetrachloride, thereby "activating" the polymer so it can react with one or more monomers.

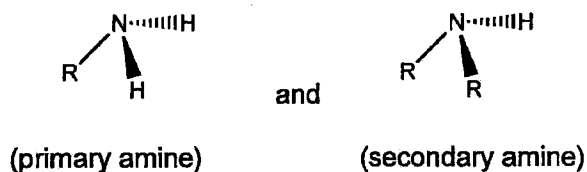
7. Reducing agents act on organic molecules in one of two ways: the agents either decrease the organic molecule's oxygen content, or increase its hydrogen content, as indicated below.



8. For example, *Hörl* demonstrates that the method disclosed therein can be used to activate nitrogen-containing polymers having polyamide groups in the side chain. See, e.g., *Hörl* at Examples. Polyamide groups do not exist in the lowest possible oxidation state and, therefore, are capable of further reduction, for example, by receiving a hydrogen atom from a reducing agent, as shown below.



9. In contrast, however, primary and secondary amines (shown below) have no oxygen molecules that can be removed by a reducing agent, and are incapable of receiving an additional hydrogen molecule from a reducing agent.



10. Thus, primary and secondary amines exist in the lowest possible oxidation state, and cannot be reduced further. Accordingly, although *Hörl* states that polymers containing primary or secondary amino groups are suitable for use in the graft polymerization method disclosed therein (see at column 5, lines 42-46), it is unclear how the reducing agents used in that method could "activate" such primary or secondary amines so they can react with one or more monomers.

11. In my opinion, one skilled in the art would not have attempted to modify the method disclosed in *Hörl* to arrive at the currently pending claims of the '703

application based solely on the unsupported statement in *Hörl* that the method can be used with polymers containing primary or secondary amino groups. One skilled in the art would have expected that the method disclosed in *Hörl* could be used to activate nitrogen-containing polymers having amide groups, sulfone groups ($\text{—SO}_2\text{—}$), and carbamic acid groups (—O—CO—NH—), as discussed in column 5 of *Hörl*, since all of those groups are capable of further reduction. However, given the chemical principles behind *Hörl*'s method, one skilled in the art would not have expected success from using the method to "activate" solid substrates containing primary or secondary amino groups. Thus, one skilled in the art would not have chosen the method disclosed in *Hörl* as a starting-point for graft polymerizing a solid substrate having primary and secondary amines, as recited in the currently pending claims of the '703 application.

13. For at least these reasons, it is my opinion that the invention recited in the currently pending claims of the '703 application is not obvious.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: December 22, 2009

By: 
Dr. Markus Storr, PhD, Dipl. Chem. (Univ.)

Dr. Markus Storr, PhD, Dipl-Chem. (Univ.)

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Profile: Markus Storr is a senior scientist and research project manager at Gambro Dialysatoren GmbH in Hechingen, Germany. Gambro is a global medical technology company and a leader in developing, manufacturing and supplying products, therapies and services for chronic and acute hemodialysis, peritoneal dialysis and hepatic care. Markus has more than 10 years work experience as R&D project leader in the development of synthetic membranes and dialyzers. In his current position he is responsible within the Gambro research organisation for the development of new therapies based on extracorporeal blood purification treatments with membrane and adsorption devices.

Education & Qualifications

PhD 1994 Technical University Munich, Thesis title: 'Development of heterogeneous biocatalysts for synthesis of a pharmaceutical agent'

Science graduate 1990 Technical University Munich, Chemistry

Professional History

Present Appointment

June 1994 - June 2000 Project Manager R&D, Gambro Dialysatoren GmbH.

Development of synthetic dialyzers

July 2000 - present Project Manager Research, Gambro Dialysatoren GmbH,
Functionalised membranes and adsorbents.

Previous Appointments.

Jan 1991-May 1994 Research Associate, Department of Technical Chemistry,
Technical University Munich.

2. August 2010
